IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC., Plaintiff, v. BIONPHARMA INC., Defendant.	)	C.A. No. 18-1962 (LPS) C.A. No. 19-1067 (LPS) C.A. No. 20-1256 (LPS) **REDACTED - PUBLIC VERSION**

PLAINTIFF SILVERGATE PHARMACEUTICAL'S ANSWERING BRIEF IN OPPOSITION TO BIONPHARMA'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT IN C.A. No. 20-1256 AND OPENING BRIEF IN SUPPORT OF ITS CROSS-MOTION FOR CONSOLIDATION

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TABLE OF CONTENTS

PAGE(S)

I. INTRODUCTION 1

II. NATURE AND STAGE OF THE PROCEEDINGS/STATEMENT OF FACTS 2

A. Asserted Patents 2

B. Status of Bionpharma's ANDA and ANDA Product 3

C. Scope of The Asserted Patents And Likelihood Of Duplicative Trials 4

III. SUMMARY OF ARGUMENT 6

IV. ARGUMENT 6

A. Legal Standards 6

1. Motion to Dismiss 6

2. Motion to Consolidate 7

B. Argument: The Court Should Deny Bionpharma's Motion to Dismiss 7

1. Silvergate Sufficiently Pled Infringement Under 35 U.S.C. § 271(e)(2) 8

a. The elements of infringement under 35 U.S.C. § 271(e)(2) do not require the submission of a Paragraph IV certification 8

b. *Vanda* is inapplicable 10

c. Efficiency and practicality warrant denial of the motion to dismiss 12

2. Declaratory Judgement Is Irrelevant 12

C. Argument: Consolidation Is Appropriate 13

1. The Cases Involve Common Questions of Law and Fact 13

2. A Decision Regarding The Original Patents Is Not Necessarily Dispositive of The New Patents 14

3. Consolidation Will Promote the Best Use of the Court's and Parties' Limited Resources, Reduce Duplicative Costs, and Promote Efficiency 144

4. The Efficiencies Vastly Outweigh Any Minor Inconvenience Resulting From Consolidation 17

V. CONCLUSION 18

TABLE OF AUTHORITIES[1]

PAGE(S)

CASES

Abbott Diabetes Care, Inc. v. Dexcom, Inc., C.A. No. 06-514 GMS,
2007 WL 2892707 (D. Del. Sept. 30, 2007) 7, 13, 15

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 6, 7, 8

AstraZeneca AB v. Dr. Reddy's Labs., Inc.,
209 F. Supp. 3d 744 (D. Del. July 20, 2016) 11

Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.,
379 F. Supp. 3d 326 (D. Del. March 31, 2019) 8

Ben Venue Labs., Inc. v. Novartis Pharm. Corp.,
146 F. Supp. 2d 572 (D.N.J. May 30, 2001) 11, 12

Bristol-Myers Squibb Co. v. Royce Labs. Inc.,
69 F.3d 1130 (Fed. Cir. 1995) 10

Bristol-Myers Squibb Co. v. Mylan Pharms. Inc., C.A. No. 17-379-LPS,
2017 WL 3980155 (D. Del. Sept. 11, 2017) 8, 12

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
566 U.S. 399 (2012) 10

Cedars-Sinai Med. Ctr. v. Revlon, Inc.,
111 F.R.D. 24 (D. Del. June 11, 1986) 15, 16

Celgene Corp. v. Sun Pharma Global FZE, C.A. No. 19-10099 (SDW) (LDW),
2020 WL 1921700 (D.N.J. April 6, 2020) 8, 9

Cephalon, Inc. v. Sandoz, Inc., Civ. No. 11-821-SLR,
2012 WL 682045 (D. Del. March 1, 2012) 11, 12

Eastman Chem. Co. v. Alphapet Inc., C.A. No. 09-971-LPS-CJB,
2011 WL 7121180 ..... *passim*

Eisai Co., Ltd. v. Mutual Pharm. Co., Inc., C.A. No. 06–3613 (HAA),
2007 WL 4556958 (D.N.J. Dec. 20, 2007) 10

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990) 10

In re Omeprazole Patent Litig.,
536 F.3d 1361 (Fed. Cir. 2008) 10

[1] All internal citations omitted, and all emphasis added unless otherwise noted.

TABLE OF AUTHORITIES
(CONTINUED)

PAGE(S)

Janssen Pharmaceutica., N.V. v. Apotex, Inc.,
540 F.3d 1353 (Fed. Cir. 2008).....10

Jazz Pharms., Inc. v. Roxane Labs., Inc., Civ. No. 10–6108–ES–SCM,
2013 WL 1596790 (D.N.J. April 12, 2013).....7, 16

Malleus v. George,
641 F.3d 560 (3d Cir. 2011).....7, 8

Masimo Corp. v. Philips Elecs. N. Am. Corp., C.A. No. 11-742-LPS-MPT,
2012 WL 1267979 (D. Del. April. 16, 2012).....15

Meds. Co. v. Eagle Pharms., Inc., C.A. No. 16-569 (SRC),
2016 WL 4418230 (D.N.J. Aug. 17, 2016) 10

Merck Sharp & Dohme Corp. v. Sandoz Inc., C.A. No. 12-3289 (PGS),
2013 WL 591976 (D.N.J. Feb. 14, 2013) 9, 12

MIG Invs. LLC v. Aetrex Worldwide, Inc.,
852 F. Supp. 2d 493 (D. Del. March 30, 2012) 16

Ortho-McNeil Pharma., Inc. v. Kali Labs., Inc., C.A. No. 02-5707 (DMC),
2007 WL 1814080 (D.N.J. June 20, 2007).....7

Par Pharm., Inc. v. Hospira, Inc., C.A. No. 17-944-JFB-SRF, 2018
WL 3343238 (D. Del. May 11, 2018).....8

Santiago v. Warminster Twp.,
629 F.3d 121 (3d Cir. 2010).....8

SZ DJI Tech. Co., Ltd. v. Autel Robotics USA LLC, C.A. No. 16-706-LPS,
2018 WL 1316203 (D. Del. March 14, 2018).....7

United States v. Dentsply Int'l., Inc.,
190 F.R.D. 140 (D. Del. Oct. 29, 1999).....16

Vanda Pharms. Inc. v. West-Ward Pharma. Int'l Ltd.,
887 F.3d 1117 (Fed. Cir. 2018).....6, 10, 11

Weller v. Wilkinson, C.A. No. 19-1723-MN-JLH,
2020 WL 2514079 (D. Del. May 15, 2020).....15

STATUTES

35 U.S.C. § 271(e) 1

35 U.S.C. § 271(e)(2)..... *passim*

35 U.S.C. § 271(e)(2)(A) 6, 10

TABLE OF AUTHORITIES (CONTINUED)

PAGE(S)

RULES

Rule 12(b)(6).....6, 7, 11

Rule 42(a).....7

TABLE OF ABBREVIATIONS

Bionpharma	Bionpharma Inc.
FDA	Food and Drug Administration
DJ	Declaratory Judgment
TRO	Temporary Restraining Order
ANDA	Abbreviated New Drug Application
the ’008 Patent	U.S. Patent No. 9,669,008
the ’442 Patent	U.S. Patent No. 9,808,442
the ’745 Patent	U.S. Patent No. 10,039,745
the ’987 Patent	U.S. Patent No. 10,154,987
Original Patents	The ’008, ’442, ’745, and ’987 patents, collectively
the ’482 patent	U.S. Patent No. 10,786,482
the ’868 patent	U.S. Patent No. 10,772,868
New Patents	The ’482 and ’868 patents, collectively
Prior Cases	C.A. No. 18-cv-1962 (LPS) and C.A. No. 19-cv-1067 (LPS)

I. INTRODUCTION

Bionpharma's motion to dismiss asks this Court to take an inefficient and impractical course instead of addressing once (and only once) the common legal issue pending in this case and related pending litigation between the parties: whether Bionpharma's ANDA product infringes patents covering Silvergate's Epaned Product. None of Bionpharma's arguments urging dismissal have any merit. The most efficient and practical course to resolve the common issues across all patents is to consolidate this case with the related matters.

Bionpharma's argument that a Paragraph IV certification on the asserted patents is always required to create a cause of action is incorrect and misstates the law. All of the Epaned patents—both those asserted in the present matter and those asserted in the related litigation—are related and expire on March 25, 2036. It is undisputed that Bionpharma filed an ANDA seeking to market a generic version of Epaned before March 25, 2036—that is all that is required to state a claim for infringement under 35 U.S.C. § 271(e).[2] Thus, the present matter is properly pled and should proceed and be consolidated with the related litigation.

Instead, Bionpharma asks the court to delay litigation regarding U.S. Patent Nos. 10,772,868 (the "'868 Patent") and 10,786,482 (the "'482 Patent") (collectively, "the New Patents"). Bionpharma provides no adequate reason for dismissal or denial of consolidation, especially in view of the significant burden that will be imposed on the Court and Silvergate if matters involving related patents and the same accused product must be resolved separately.

Bionpharma's only remaining argument is the flawed assumption that the related case resolution will resolve all issues on the New Patents so there is no need to adjudicate the New

[2] Bionpharma does not state in its opening brief that it has or intends to file a Paragraph III certification—only that it has not yet certified under Paragraph IV.

Patents now. Bionpharma is once again incorrect. Bionpharma raised only [redacted] non-infringement arguments regarding U.S. Patent Nos. 9,669,008 (the "'008 Patent"); 9,808,442 (the "'442 Patent"); 10,039,745 (the "'745 Patent"); and 10,154,987 (the "'987 Patent") (collectively, "the Original Patents"); arguments that are potentially mooted by the difference in claim scope in the New Patents. Thus, while the New Patents have the same specification and many of the same elements as the Original Patents, there are key differences in the claim limitations on which Bionpharma has rested its defenses. In other words, if Bionpharma loses on [redacted] arguments, there is still a patent—one of the two new patents—covering its ANDA product. Given this reality, lack of consolidation of these matters would lead to a significant risk that Silvergate would need to seek a preliminary injunction while the New Patents are in litigation.

The most efficient and practical course forward is to resolve the question of infringement at the same time for all related patents. These cases involve the same parties, the same accused products, the same underlying technology, the same acts of infringement, and the same patent family. Due to the extreme overlap of factual and legal issues, these cases will involve the same witnesses, documents, experts, and substantially related infringement and non-infringement theories. Thus, Bionpharma's motion to dismiss should be denied and Silvergate's cross-motion to consolidate should be granted.

II. NATURE AND STAGE OF THE PROCEEDINGS/STATEMENT OF FACTS

This is a Hatch-Waxman litigation that relates to Bionpharma's generic version of Silvergate's Epaned product.

A. Asserted Patents

On December 12, 2018, in response to a Paragraph IV Notice Letter, Silvergate filed suit against Bionpharma for infringement of the '008 Patent, the '442 Patent, and the '745 Patent. C.A.

18-1962, D.I. 1.[3] Six days later, the '987 Patent issued. Four months later, Bionpharma sent a Notice Letter regarding the '987 Patent, and Silvergate filed a new suit, which was consolidated with the first. C.A. No. 19-1067, D.I. 1.

On September 15, 2020 and September 29, 2020, respectively, the '868 Patent and '482 Patent issued.[4] Silvergate filed suit alleging infringement of the '868 Patent on September 18, 2020 and amended that complaint to assert the '482 patent on September 29, 2020. C.A. No. 20-01256, D.I. 1, 7. Recognizing that the most efficient course would be to address all patents in a single trial, and that the New Patents have a different claim scope than the Original Patents, Silvergate attempted to negotiate a consolidated schedule. Bionpharma rejected that offer and filed the instant motion.

B. Status of Bionpharma's ANDA and ANDA Product

Although Bionpharma repeatedly states that it has not yet certified under Paragraph IV on the New Patents, not once does it state that it is going to certify Paragraph III. Additionally, during the parties' meet and confer on Silvergate's motion for consolidation (before Bionpharma filed its motion to dismiss), counsel for Bionpharma suggested it may be willing to consider consolidation if Silvergate agreed to sufficiently narrow the asserted claims at issue across all of the Original Patents and New Patents. Although Bionpharma quickly retracted that proposal, this suggestion would be nonsensical if Bionpharma were intending to certify under Paragraph III on the New Patents. Finally, as noted above, all the patents – both old and new – have the same expiration date.

The 30-month regulatory stay of approval of Bionpharma's ANDA expires on April 30,

[3] [redacted]

[4] The '868 Patent is listed in the Orange Book for Epaned. Silvergate requested Orange Book listing of the '482 Patent and expects that listing will become publicly available shortly.

2021, and trial regarding the '745 and '987 Patents is set to begin on February 1, 2021. Bionpharma's motion does not state whether it expects to receive FDA approval before April 30, 2021. Moreover, Bionpharma objects to Silvergate including any mention of the current status of Bionpharma's ANDA application in the present pleadings. *See* Ex. A. Thus, the Court and Silvergate must assume that Bionpharma could receive FDA approval at any time, and that emergency TRO/preliminary injunction motion practice may be necessary if all issues related to all asserted patents are not resolved.

C. Scope of The Asserted Patents and Likelihood of Duplicative Trials

The scope of the claims in the New Patents (the '868 Patent and the '482 Patent) are different from the scope of the claims in the Original Patents (the '745 Patent and the '987 Patent). These differences in scope are directly relevant to Bionpharma's defenses. Specifically, with respect to the Original Patents, [redacted] C.A. No. 20-01256, D.I. 10 at 3. The relevant differences in the claims is summarized in the below chart:

Limitation	'745 Patent / '987 Patent Representative Claim	'868 Patent Representative Claim	'482 Patent Representative Claim
[redacted]	[redacted]	[redacted]	[redacted]

Limitation	'745 Patent / '987 Patent Representative Claim	'868 Patent Representative Claim	'482 Patent Representative Claim
	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]

Regarding the [redacted] limitation of the '745 and '987 Patents, Bionpharma argues that prosecution history estoppel prevents capture of equivalents and that the accused component of its ANDA product is not equivalent [redacted] C.A. No. 20-01256, D.I. 10 at 4. With respect to the [redacted] limitation, Bionpharma argues that the [redacted] in the ANDA product is not equivalent to the claimed [redacted] and that Silvergate cannot capture such an equivalent because [redacted] is disclosed in the specification.[5] *Id.* As is

[5] Silvergate disputes each of these arguments.

evident from the above table, Bionpharma's defenses are not entirely applicable to the New Patents.

III. SUMMARY OF ARGUMENT

1. Bionpharma's motion to dismiss should be denied because Silvergate has properly pled infringement pursuant to 35 U.S.C. § 271(e)(2)(A) because it has pled that Bionpharma has filed an ANDA with the purpose to market its ANDA Product before the expiration of the patents-in-suit.

2. Silvergate's motion to consolidate should be granted because the litigations involve the same ANDA, the same parties, and the same patent family and thus involve common questions of law and fact such that consolidation will promote judicial efficiency and any minor inconvenience inured by consolidation is outweighed by the benefits.

IV. ARGUMENT

A. Legal Standards

1. Motion to Dismiss

35 U.S.C. § 271(e)(2)(A) states:

> It shall be an act of infringement to ***submit an application*** under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval, . . . to engage in the commercial manufacture, use, or sale of a drug, . . . before the expiration of such patent.

Under Federal Circuit law, jurisdiction exists in this exact situation: where a patent issued after the ANDA was filed, and the suit was filed before the Paragraph IV certification was made to the new patent. *Vanda Pharms. Inc. v. West-Ward Pharma. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) ("Here, Vanda's complaint alleged that West-Ward infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA. ***Nothing more was required to establish the district court's subject matter jurisdiction***.").

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). For a Rule 12(b)(6) motion to dismiss, the Court must accept all allegations in the complaint as true. *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011).

2. Motion to Consolidate

Rule 42(a) grants district courts "authority to consolidate actions involving a common question of law or fact." *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, C.A. No. 06-514 GMS, 2007 WL 2892707, at *3 (D. Del. Sept. 30, 2007). "[C]ourts balance considerations of 'efficiency, expense, and fairness,'" when determining whether to consolidate cases. *See SZ DJI Tech. Co., Ltd. v. Autel Robotics USA LLC*, C.A. No. 16-706-LPS, 2018 WL 1316203, at *1 (D. Del. March 14, 2018) (quoting *Abbott*, 2007 WL 2892707, at *3). In patent cases, motions to consolidate are favored when the actions involve the same parties, same technology, same patent or patent families, and same accused product. *E.g.*, *Eastman Chem. Co. v. Alphapet Inc.*, C.A. No. 09-971-LPS-CJB, 2011 WL 7121180, at *3-4 (same technology, same patent family, same accused product); *see also SZ DJI*, 2018 WL 1316203, at *1 ("The parties involved are exactly the same, the patents share common applicants, inventors, and priority periods and . . . the accused products are identical."); *Ortho-McNeil Pharma., Inc. v. Kali Labs., Inc.*, C.A. No. 02-5707 (DMC), 2007 WL 1814080, at *6 (D.N.J. June 20, 2007) (same); *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, Civ. No. 10–6108–ES–SCM, 2013 WL 1596790, at *3 (D.N.J. April 12, 2013) (same).

B. Argument: The Court Should Deny Bionpharma's Motion to Dismiss

The Court should deny Bionpharma's Motion to Dismiss because (1) Silvergate has properly pled infringement under the Hatch-Waxman Act and (2) declaratory judgment is irrelevant.

1. Silvergate Sufficiently Pled Infringement Under 35 U.S.C. § 271(e)(2)

Bionpharma's motion to dismiss should be denied because Silvergate appropriately pled patent infringement under § 271(e)(2). Ruling on a Rule 12(b)(6) motion entails a three-step inquiry: (1) a court must determine the elements of the stated cause of action; (2) the court must reject any conclusory allegations; and (3) assuming the truthfulness of "well-pleaded factual allegations," the court must "determine whether they are sufficiently alleged to state a claim for relief." *Par Pharm., Inc. v. Hospira, Inc.*, C.A. No. 17-944-JFB-SRF, 2018 WL 3343238, at *2 (D. Del. May 11, 2018) (citing *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010); *Ashcroft*, 556 U.S. at 675; *Malleus* 641 F.3d at 563). "The third prong presents a context-specific inquiry that 'draw[s] on [the court's] experience and common sense.'" *Par Pharm.*, 2018 WL 3343238, at *2 (alterations in original) (quoting *Iqbal*, 556 U.S. at 679). Construing all allegations in the complaint as true, Silvergate properly pled infringement under 35 U.S.C. § 271(e)(2) by pleading that Bionpharma submitted an ANDA seeking approval to market a product before the expiration of the Epaned patents. *See, generally,* C.A. No. 20-01256, D.I. 1, 7.

a. The elements of infringement under 35 U.S.C. § 271(e)(2) do not require the submission of a Paragraph IV certification

The Hatch-Waxman Act defines infringement as "[t]he submission ***of an ANDA*** to the FDA, if the ANDA seeks approval before the expiration of a patent covering the branded drug to which the generic product is bioequivalent." *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, C.A. No. 17-379-LPS, 2017 WL 3980155, at *7 (D. Del. Sept. 11, 2017); *see also Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331 (D. Del. March 31, 2019) ("Under the [Hatch-Waxman] Act, filing an ANDA or a paper NDA constitutes an artificial but justiciable act of patent infringement."). Submission of a Paragraph IV certification is not an element of infringement under 35 U.S.C. § 271(e)(2). *Celgene Corp. v. Sun Pharma Global FZE*,

C.A. No. 19-10099 (SDW) (LDW), 2020 WL 1921700, at *2 (D.N.J. April 6, 2020) ("Thus, the plain text of the Hatch-Waxman Act does not require the submission of a Paragraph IV certification to the FDA to commit the technical 'act of infringement' . . . nor does it require that the asserted patent be listed in the Orange Book.").[6]

Here, Silvergate pled that (1) Bionpharma submitted an ANDA seeking approval for a generic version of Silvergate's Epaned Product (C.A. No. 20-01256, D.I. 7 at ¶¶ 1, 17-18, 24, 29); (2) the New Patents cover Silvergate's Epaned Product (C.A. No. 20-01256, D.I. 7 at ¶ 16); and (3) upon FDA approval, Bionpharma's ANDA Product would infringe the New Patents (C.A. No. 20-01256, D.I. 7 at ¶¶ 20-21, 25-27, 30-32). The Hatch-Waxman Act requires nothing further to demonstrate a claim for infringement.

Additionally, Bionpharma tellingly did ***not*** say that it intends to provide a Paragraph III certification to the New Patents, only that it had not ***yet*** provided a Paragraph IV certification. On the meet and confer, Bionpharma indicated it may be willing to consider consolidation of the litigations if Silvergate reduced the total asserted claims between all asserted patents in order to narrow the issues at trial. Such an offer indicates that Bionpharma does intend to provide a Paragraph IV certification, or the anticipation of litigation on these patents would be meaningless. Furthermore, the New Patents are terminally disclaimed to prior patents in the chain and expire the same day as the Original Patents. Because Bionpharma has previously provided Paragraph IV certifications to the Original Patents, Bionpharma has unequivocally stated that they intend to market the product before the expiration of the New Patents.

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[6] While all patents at issue here have been submitted for Orange Book listing, 35 U.S.C. § 271(e)(2) does not require that an asserted patent appear in the Orange Book. *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, C.A. No. 12-3289 (PGS), 2013 WL 591976, at *4 (D.N.J. Feb. 14, 2013) ("Nothing in the plain language [of §271(e)(2)] suggests that infringement actions against ANDA filers **must be based only on Orange Book listed patents**.").

(continued...)

b. *Vanda* is inapplicable

Bionpharma's almost exclusive reliance on *Vanda* is fatal to its motion. First, Bionpharma misstates the issues and holding of *Vanda*.[7] Second, *Vanda* is inapplicable because of the procedural and factual differences here.

In *Vanda*, the Federal Circuit addressed a case where one patent was Orange Book listed at the time that the ANDA was filed, and another patent issued during litigation, and was added to the litigation prior to filing of a Paragraph IV certification by the ANDA filer. The Federal Circuit held, *inter alia*, that (1) the district court had jurisdiction over the dispute regarding the second patent even though it was filed before submission of a Paragraph IV certification; and (2) "an application" as stated in § 271(e)(2)(A) includes amendments of an ANDA. *Vanda*, 887 F.3d at 1125, 1128. Contrary to Bionpharma's assertions, *Vanda* did ***not*** hold that infringement occurred ***only*** after the ANDA was amended. C.A. No. 20-01256, D.I. 10 at 8. Likewise, *Vanda* did ***not*** hold that infringement does not "accrue until the Paragraph IV certification" is filed. *Id.* Nowhere

[7] None of the other cases Bionpharma mentions in its motion support its arguments either because (1) none of them limit the infringing acts under § 271(e)(2) to ***only*** the filing of an ANDA or a Paragraph IV certification, and (2) none deal with the situation where a patentee asserts a later issued patent against an ANDA filer, as here. Bionpharma generally quotes dicta, ignoring the actual issues disputed and decided in the cases it relies upon. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (holding the § 271(e)(1) safe-harbor provision applies to medical devices); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012) (finding a proper cause of action to force a brand manufacturer to change its use codes); *Bristol-Myers Squibb Co. v. Royce Labs. Inc.*, 69 F.3d 1130, 1134 (Fed. Cir. 1995) (holding the URAA did not exempt ANDA filer's infringement); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1363-64 (Fed. Cir. 2008) (holding covenants not to sue between the patentee and ANDA filer deprived court of subject matter jurisdiction); *In re Omeprazole Patent Litig.*, 536 F.3d 1361, (Fed. Cir. 2008) (holding district court had jurisdiction after the patents expired, the evidence supported infringement and the claims were not invalid). Moreover, *Eisai* is distinguishable because the patentee there twice failed to list the patent at issue in the Orange Book. *Eisai Co., Ltd. v. Mutual Pharm. Co., Inc.*, C.A. No. 06–3613 (HAA), 2007 WL 4556958, at *14 (D.N.J. Dec. 20, 2007). Furthermore, the Court later noted that *Eisai* "appear[s] to run contrary" to Federal Circuit guidance. *See Meds. Co. v. Eagle Pharms., Inc.*, C.A. No. 16-569 (SRC), 2016 WL 4418230, at *2, n.1 (D.N.J. Aug. 17, 2016).

did the *Vanda* court state that an act of infringement under § 271(e)(2) requires submission of a Paragraph IV certification.

Moreover, *Vanda* does not stand for the proposition that the absence of a Paragraph IV certification "'raise[s] potential merits problems'" such that dismissal at the pleadings stage is warranted. *Id.* Rather, *Vanda* stated that arguments made by the ANDA filer in that matter regarding "whether there was a qualifying act of infringement raise potential merits problems, not jurisdictional issues" and thus were not relevant to the jurisdictional analysis. *Vanda*, 887 F.3d at 1124. It is inappropriate to consider whether a complaint will succeed on the merits to pass 12(b)(6) scrutiny. *AstraZeneca AB v. Dr. Reddy's Labs., Inc.*, 209 F. Supp. 3d 744, 752 (D. Del. July 20, 2016) ("The court's determination [on a 12(b)(6) motion] is not whether the non-moving party 'will ultimately' prevail."). Thus, Bionpharma's suggestion that the merits of the Amended Complaint should be evaluated is not only unsupported but contrary to law.

The notion that a Paragraph IV certification is a required precursor to an infringement suit under § 271(e)(2) elevates form over substance and is unpersuasive. *Cephalon, Inc. v. Sandoz, Inc.*, Civ. No. 11-821-SLR, 2012 WL 682045, at *5 (D. Del. March 1, 2012) (denying motions to dismiss under both 12(b)(1) and 12(b)(6) and noting that, "It would be ironic, indeed, if the absence of [] a Paragraph IV certification precluded suit, when the certification provisions exist for the benefit of the patentee. **I decline to elevate form over substance where the purpose of administrative process has been served**.")[8]; *see also, Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 582 (D.N.J. May 30, 2001) ("Since the certification provisions exist

[8] Bionpharma's attempt to distinguish *Cephalon* as limited to subject matter jurisdiction (C.A. No. 20-01256, D.I. 10 at 8 n.4) fails, as *Cephalon* clearly states that "Because Sandoz bases its argument for dismissal pursuant to Fed. R. Civ. P. 12(b)(6) on the same reasoning rejected above for lack of jurisdiction, to wit, the complaint fails to state a cause of action for infringement because Sandoz's ANDA does not contain a Paragraph 4 certification with respect to [the patents], its motion to dismiss on this ground is likewise denied." 2012 WL 682045, at *6 n.10.

(continued...)

for the benefit of the patentee, a court could conclude that a patentee should be allowed to sue for infringement **as soon as the ANDA filer has left the safe harbor of § 271(e)(1) by filing a potentially infringing ANDA**.").[9]

c. Efficiency and practicality warrant denial of the motion to dismiss

Considerations of policy and efficiency weigh against dismissal. *Merck*, 2013 WL 591976, at *4 (denying a motion to dismiss infringement action with no Paragraph IV certification because of "the concept of judicial efficiency and common sense."). The pending litigations involve the same ANDAs, the same parties, and the same patent family, thus Bionpharma will likely "allege [] the same defenses and will have to present the same case in order to prevail on both claims." *Id.* As in *Merck* "the overlap [here] weighs in favor of trying the two infringement claims together." *Id.*[10] Resolving all allegations of infringement simultaneously is also consistent with the policy behind the Hatch-Waxman Act. *Id.*; *see also Bristol-Myers*, 2017 WL 3980155, at *7 ("This 'highly artificial act of infringement' precipitates litigation between the branded drug company and the generic drug company for the express purpose of resolving patent disputes ***before*** a generic product is launched.").

2. Declaratory Judgement Is Irrelevant

Having reached the incorrect conclusion that a Paragraph IV certification is always a prerequisite to a claim for patent infringement under § 271(e)(2), Bionpharma further incorrectly argues that Silvergate is required to plead declaratory judgment claims to seek relief for

[9] This factor is especially important considering Bionpharma's four-month delay in filing a Paragraph IV certification to incorporate the '987 Patent in the Second Litigation. Dismissing the case here for a lack of a Paragraph IV certification while allowing Bionpharma to wait until it chooses to certify the Asserted Patents would allow Bionpharma to inappropriately "control the fact and scope of litigation." *Cephalon*, 2012 WL 682045, at *5 n.9.

[10] *See also*, § IV.C *infra*.

Bionpharma's infringement of the New Patents. Bionpharma is wrong. As discussed above, Silvergate properly pled claims for infringement of the New Patents under 35 U.S.C. § 271(e)(2). Indeed, it is undisputed that Bionpharma filed an ANDA seeking FDA approval for its generic Epaned product. It is also undisputed that Bionpharma is seeking that approval prior to March 25, 2036—the expiration date of both the Original Patents and the New Patents. Declaratory judgment claims are irrelevant and unnecessary because Bionpharma's infringement is already addressed in Silvergate's properly pled § 271(e)(2) infringement claims.[11]

C. Argument: Consolidation Is Appropriate

The cases should be consolidated because (1) they involve common questions of law and fact; (2) consolidation will promote judicial efficiency; and (3) any minor inconvenience inured by consolidation is outweighed by the benefits.

1. The Cases Involve Common Questions of Law and Fact

The threshold question for consolidation is whether the separate cases involve common questions of law or fact. *Eastman*, 2011 WL 7121180, at *2. As discussed above, they do. Bionpharma expressly admits that the newly filed lawsuit "involves newly issued patents that are related to, and claim essentially, the same subject matter that are the subject of pending litigation between the parties and before this Court." C.A. No. 20-01256, D.I. 10 at 1. Cases that involve the same patents, the same technology, related infringement theories and accused products, and the same parties, such as here, are the exact type of cases where "judicial resources likely will be conserved by consolidat[ion]." *Abbott*, 2007 WL 2892707, at *4. Therefore, because consolidation will increase judicial efficiency, these matters should be consolidated.

[11] To the extent that the Court finds that declaratory judgment pleading is necessary, Silvergate respectfully requests leave to amend to add such claims.

2. A Decision Regarding The Original Patents Is Not Necessarily Dispositive of The New Patents

As discussed above, the claims of the New Patents have a different scope than the claims of the Original Patents, and that scope is directly relevant to Bionpharma's non-infringement defenses. *Supra*, § II.C. Given these facts, Bionpharma's contention that collateral estoppel will necessarily bar litigation regarding the New Patents following resolution of the disputes regarding the Original Patents is incorrect.

Even if that were accurate, Bionpharma only considers half of the possible outcomes – that it could lose both of its arguments (in which case it could not launch any ANDA product) or that it could win both arguments (which, according to Bionpharma, means it "wins" on the New Patents). Bionpharma ignores that there are two other possible outcomes: (1) Bionpharma proves its defenses only with respect to the [redacted] limitation, which is irrelevant to [redacted]; or (2) Bionpharma proves its defenses only with respect to the [redacted] limitation, which is irrelevant to [redacted]. In other words, there are two potential outcomes that will necessitate further litigation regarding the one or both of the New Patents. Thus, delaying litigation on the New Patents does not make sense and would result in unnecessary waste of judicial and party resources.[12]

3. Consolidation Will Promote the Best Use of the Court's and Parties' Limited Resources, Reduce Duplicative Costs, and Promote Efficiency

The commonalities between these cases present at least six reasons why consolidation will result in increased efficiency and reduce duplicative costs.

First, judicial resources are best conserved by consolidating cases when they involve

[12] Bionpharma's contention that findings regarding the claims of the Original Patents will impact analysis of the New Patents is reason to consolidate, not reason to delay trial on some patents.

"related technologies. . ., [when] all claims of infringement are based on the same device, and [when] both cases involve the same part[y]." *Abbott*, 2007 WL 2892707, at *4. Here, the cases involve the same enalapril ready-to-use oral formulation technology and the same claims of infringement based on filing of Bionpharma's ANDA. Moreover, the cases involve the same parties, same patent family, same witnesses, and same documents. Therefore, consolidation will best conserve judicial resources. *Cedars-Sinai Med. Ctr. v. Revlon, Inc.*, 111 F.R.D. 24, 33 (D. Del. June 11, 1986) (ordering consolidation because "the inventions were by the same inventor, and . . . much of the prior art will be the same for the two patents."); *see also Weller v. Wilkinson*, C.A. No. 19-1723-MN-JLH, 2020 WL 2514079, at *2 (D. Del. May 15, 2020) (ordering consolidation because "[t]he complaints name the same defendants, **they allege similar (if not identical) facts**, and they contain overlapping [legal] claims.").

Second, trying these cases separately would result in massively duplicative discovery. Because the patents all belong to the same family and involve the same inventors, discovery regarding prosecution and development of the invention has already occurred. Silvergate already produced documents and witnesses related to the development of Epaned. Bionpharma already produced documents regarding its ANDA. These matters should be consolidated to avoid such needless, duplicative discovery. *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, C.A. No. 11-742-LPS-MPT, 2012 WL 1267979, at *4 (D. Del. April. 16, 2012) (ordering consolidation even though "the two matters involve different patents with different claims" because "the issues in both cases are closely intertwined, and likely will involve the same witnesses **and similar documentary evidence and exhibits**."); *Eastman*, 2011 WL 7121180, at *5 (ordering consolidation because "document discovery is also likely to overlap considerably . . . given that the same conduct. . . is at issue in both actions and that at least two of the five asserted patents are directly related."); *MIG*

Invs. LLC v. Aetrex Worldwide, Inc., 852 F. Supp. 2d 493, 515 (D. Del. March 30, 2012) (ordering consolidation because "there will be overlap in deposition discovery . . . as well as documentary evidence and other discovery."); *United States v. Dentsply Int'l., Inc.*, 190 F.R.D. 140, 143 (D. Del. Oct. 29, 1999) ("The three cases require discovery of many of the same [] documents.").

Third, without consolidation, the cases will necessarily involve the exact same witnesses giving almost identical testimony at two separate trials. The Original Patents and the New Patents involve the same inventors and the cases will involve many of the same or similar issues. Courts have ordered consolidation when allowing cases to proceed separately would cause duplicative trial testimony in the separate actions. *Eastman* 2011 WL 7121180, at *5 (ordering consolidation because "there are likely to be a number of witnesses whose testimony will be relevant to both [actions]."); *Jazz Pharms.*, 2013 WL 1596790, at *3 (ordering consolidation because "it is likely that there will be considerable overlap between the evidence used in both actions.").

Fourth, "the [legal] claims in each case are similar and arise from the same alleged conduct" by Bionpharma. *Dentsply Int'l*, 190 F.R.D. at 143. The act of patent infringement in each case arises from Bionpharma's filing of ANDA No. 212408 seeking approval to market a generic version of Silvergate's Epaned product. The similarity of Bionpharma's infringing conduct in both cases warrants consolidation.

Fifth, consolidating these cases will eliminate the need to have a trial about a prior trial (*i.e.*, eliminate the need to resolve collateral estoppel issues). Courts have granted motions for consolidation when collateral estoppel could create issues in later filed cases. *E.g., Cedars-Sinai*, 111 F.R.D. at 33. Bionpharma suggests that if its motion is granted, it intends to argue that collateral estoppel arising from the Original Patents applies to the New Patents. C.A. No. 20-01256, D.I. 10 at 15. Such a separate litigation arguing over whether the identical issues in similar

patents from the same family were in fact litigated can be completely avoided by simply resolving all patents at once.

Sixth, consolidating these cases will avoid uncertainty (and the potential for preliminary injunction motion practice) in the period between a first and second trial. If trial regarding the Original Patents does not resolve all issues with respect to the New Patents (which, as discussed above, is a real possibility), Silvergate may need to seek a preliminary injunction to prevent launch of Bionpharma's ANDA product while litigation on the New Patents proceeds. Such motion practice would be a significant, unnecessary burden on the Court and the parties.

4. The Efficiencies Vastly Outweigh Any Minor Inconvenience Resulting From Consolidation

The efficiencies outlined above far outweigh any inconvenience or prejudice which might occur, especially considering that consolidation would not lead to a significant delay.[13] At present time, the deadline to serve the final round of expert reports is approaching, but no expert depositions have been taken. Silvergate proposed the following schedule to Bionpharma, which allows for supplementation of expert reports to address the New Patents, and trial as early as May 2021:[14]

November 19, 2020 - opening reports
December 17, 2020 - rebuttal reports
February 4, 2021 - reply reports
March 4, 2021 - close of expert discovery

This proposed schedule barely disturbs the current schedule. *Eastman*, 2011 WL 7121180, at *8 (noting that the proposed consolidated schedule "will not likely result in undue delay."). Moreover, any delay is outweighed by the benefits of consolidation, including (1) resolving all

[13] Under Silvergate's proposed schedule, the trial would begin early May—a delay of just over three months.

[14] While Silvergate is open to building in time for limited additional fact discovery, Silvergate does not think it is necessary. Bionpharma did not provide a response to this schedule proposal.

common issues regarding infringement across all patents; (2) avoiding confusion with regards to injunctions and collateral estoppel; and (3) obviating the need to hear similar testimony from the same witnesses on the same issues at multiple trials.

V. CONCLUSION

For the foregoing reasons, Silvergate respectfully requests that this court **deny** Bionpharma's motion to dismiss and **grant** Silvergate's cross-motion for consolidation.

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